

REMARKS

The Applicants thank the Examiner for his time during the telephonic interview related to this case and his careful analysis of the claims. The Applicants have amended the claims as set forth above to eliminate the use of aryl sulfonic acids in the method of the preparation of membranes. The Applicants have added a two new claims, dependent on claim 15, directed to the use of ethane sulfonic acid and trifluoromethanesulfonic acid as the sulfonic acids of the instant invention. A new set of claims (claims 29-37) have been added that parallel the original claims 15-20, 25 and 26, further containing the limitation that the membrane must have a flux of "at least 15 gfd," rather than "about at least 15 gfd." The Applicants submit that in view of the forgoing amendments and following arguments that the application is now in proper form for allowance.

Rejections under 35 U.S.C. 102(b)

The Examiner has rejected claims 15-20, 25 and 26 under 35 U.S.C. 102(b) as being anticipated by Chau (USP 4,983,291). An informal communication was filed with the Examiner on January 22, 2004 (copy enclosed as Appendix A, including references, to be entered into the case) presenting a number of arguments regarding the non-specificity of the teachings of Chau regarding sulfonic acids. The Applicants submitted that one skilled in the art would not be motivated to select the specific classes of sulfonic acids listed in claim 15, specifically C₁ to C₆ alkyl, alkenyl, haloalkyl, haloalkenyl, or hydroxy sulfonic or disulfonic acids based on the teachings of Chau. The Examiner stated by telephone that the specific example of PTSA (see table 4) fell within the limitations of claim 15 and was sufficient to result in the rejection of the claim under 102(b). Therefore, the arguments presented by the Applicants regarding the non-specificity of the teachings of Chau were not relevant.

The Applicants respectfully submit that the limitations of claim 15 were not previously met by the Chau reference, and with the limitation of aryl sulfonic acids from the

claim, PTSA no longer falls within the limitations of the claim. Similarly, claim 29 is differentiated from Chau for the reasons set forth above.

In his rejections, the Examiner pointed to the general teachings of Chau and suggested that the working examples contain examples of membranes that show a salt rejection of at least 25% and a flux of about at least 15 gfd under the conditions stated in the claims. In all of the working examples presented, the only example using a sulfonic acid was one teaching of the use of PTSA. The treatment resulted in a membrane with a flux of 13.57gfd when adjusted for the salt concentrations used in the claims (calculations were presented in the Informal Communication filed on October 15, 2003, copy enclosed as Appendix B to be entered into the case). No other specific data were presented on sulfonic acids.

On the top of page 5 of the informal communication sent to the Examiner on January 21, 2004, the Applicants submitted that 13.57 gfd does not fall within the range of "about at least 15 gfd" and requested that the Examiner demonstrate that one skilled in the art would consider 13.57 gfd to fall within the range of about at least 15 gfd, noting that all of the data presented in Chau are to a tenth of a gfd. The Applicants have also added claim 29 which includes the limitations of claim 15, but instead recites "at least 15 gfd," rather than "at least about 15 gfd." Therefore, this claim clearly does not fall within the scope of Chau. The only membrane to meet the functional requirements of the claim were membranes treated with a solutions of 2 or 5% citric acid. Both treatments resulted in a membranes with the required flux characteristics of the claims (21.8-19.0 gfd with a 2.1-3.5% salt passage under the conditions of claim 15; see table 2). However, citric acid is not a sulfonic acid, and the usefulness of citric acid in the preparation of membranes provides no suggestion for the use of sulfonic acids.

The Applicants have amended claim 15 to eliminate the use of aryl sulfonic acids. Claim 29 similarly does not recite the use of aryl sulfonic acids. Therefore, the specific example of PTSA does not fall within the limitations of the claims, as it meets neither the

chemical nor the functional limitations required by the claim. Therefore, the rejection of claim 15 under 35 U.S.C. 102(b) is traversed, and claim 29 is clearly distinguished from Chau. As the remaining claims in the rejection are dependent on the now allowable claim 15, the rejection of claims 16-20, 23 and 25 are traversed. Similarly, claims 27-28 and 30-37 are not anticipated in view of the prior art.

Rejections under 35 U.S.C. 103(a) over Chau

In view of the traversal of the rejection of 102(b), the Applicants will further demonstrate that the invention of the instant application is further non-obvious in view of Chau. *In re Rouffet*, Fed. Cir., No. 97-1492 (1998) the Court held that:

To prevent the use of hindsight based on the invention to defeat patentability of the invention, the Court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that they skilled artisan, confronted with the same problem as the inventor and not knowledge of the claimed invention, would select elements from the cited prior art references for combination in the manner cited.

[The Board] relied upon the high level of skill in the art to provide necessary motivation. The Board did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination... If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance... the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of a legal test for obviousness.

If a rejection under 35 USC 103(a) is made by the Examiner, it is requested that the Examiner indicate where in the reference motivation is found to perform the method of the invention in view of the *In re Rouffet* decision and the broad teachings of the reference.

The number of compounds taught by Chau make it impossible, without undue

experimentation, to discover the method of the invention that produces membranes with the desired characteristics, using sulfonic acids. This lack of obviousness is perhaps best demonstrated by the inability of the owners of the Chau patent, Koch Membrane Systems, Inc., (hereinafter Koch, (chain of title attached as Appendix C) to prepare a membrane with the desirable characteristics of the membranes of the instant invention. A comparison between the membrane of the instant invention and that of Koch was performed by an independent agent. The results are presented in the Secondary Considerations portion of the response. Briefly, the Hydranautics membrane was found to outperform that of Koch. As a result, a substantial contract to provide membranes for a water treatment facility was lost by Koch, and won by Hydranautics, Inc. (hereinafter Hydranautics), based on the membrane of the instant invention. If the Chau reference made obvious the membranes of the instant invention, the Applicants submit that the contract should have been won by Koch.

The court postulates three situations that seem to lead to the conclusion that it would have been obvious to try: (1) to vary all parameters or try each of numerous possible choices until one possibility arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful; (2) to explore a new technology or general approach seemed to be a promising field of investigation, where the prior art gave only general guidance as to the particular form that the claimed invention or how to achieve it; and (3) where the reference contained detailed, enabling methodology for practicing the claimed invention and a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful. The first two situations result in non-obviousness, while the third does not. (*In re O'Farrell*, 853 F.2d, 894, 7 USPQ2d 1637 (Fed. Cir. 1988)). The Applicants submit that the Chau reference does not fall into the third situation. Therefore, the claims of the instant application are not obvious in view of Chau.

The lack of a *prima facie* obviousness of the claims of the instant invention are

germane to the case if the claims are rejected for obviousness rather than anticipation. It is requested that the Examiner reconsider these arguments in view of the forgoing arguments and amendments to the claim.

Election of Species

The Applicants request that the Examiner consider the chart in the MPEP under section 2144.08(III). A flow chart is provided for the determination if a species or subclass is obvious in view of a genus. The Applicants submit that by the use of this chart, the selection of the specific subclass of the C₁-C₆ sulfonic acids, and especially the specific compounds claimed in this invention cannot be considered obvious. The text of the inquiries from the MPEP is in italics.

II.A.4.a. Is Genus So Small That Each Member is Inherently Disclosed?

No. Chau teaches a number of large classes of compounds. The Applicants submit that preparation of an exhaustive list of all of the compounds that would fall within the classes listed by Chau would be a substantial undertaking.

In *In re Jones*, 958, F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), the claimed compound fell within a genus of compounds disclosed in a prior art reference. The reference also disclosed that the genus had the same utility as that of the claimed species and was structurally similar. Nonetheless, no case of prima facie obviousness had been made out. For one thing, the reference genus may well have been infinite in scope; for another, there was no evidence, other than the PTO's speculation, that one of ordinary skill would have been motivated to make the modifications to the prior art necessary to arrive at the claimed compound.

The Applicants submit that the essentially infinite genus of compounds taught by Chau for the treatment of membranes makes the claims of the instant application non-obvious.

II.A. 4.b Are There Express Teachings That Would Have Motivated the Selection?

No. Many classes of compounds are taught. In order for the instant invention to be obvious in view of the Chau reference, one would first need to be motivated to select sulfonic acids, and then further select compounds that were not listed in the specification of Chau. The membranes that demonstrate the highest flux in Chau are those treated with citric acid, not with sulfonic acids. Sulfonic acids are substantially more expensive than citric acid. Organic sulfonic acids, as required by the limitations of the claims of the instant application, require special handling and disposal. The only sulfonic acid specifically taught by Chau does not meet the functional limitations of the claim. When a chemical compound falling within the broad or general class (disclosed in a prior art reference) is inoperative for the purpose claimed by an applicant against whom the reference is cited, operativeness of a different chemical compound (even though included in the same broad general class) for the purpose claimed by the applicant is unexpected and therefore patentable over such a reference. *Douglas Aircraft Co., Inc. v. Mueller*, 194F. Supp 268, 130 U.S.P.Q. 426, 430 (D.C. 1961). Therefore, as the sulfonic acid taught by Chau is inoperative in the method of the invention, the operability of the specific sulfonic acids claimed in the instant invention is unexpected, and therefore patentable.

There is no motivation to select sulfonic acids over the other classes taught, or to select the specific subgroup of sulfonic acids claimed in the instant invention. None of the compounds listed in claim 15 or 28 are specifically named in the Chau reference. No subclasses are defined in Chau based on the number of carbons or other factors.

II.A.4.c. Is there a teaching of structural similarity?

No. There is not substantial, overall structural similarity between the specific compounds claimed in the instant invention and the broad teachings of Chau. Moreover, there is little structural similarity between the many classes of compounds taught by Chau that could suggest the use of low molecular weight organic, sulfonic acids. The only property that the compounds of Chau have in common is that they are all hygroscopic. If one were motivated by Chau to investigate the use of sulfonic acids for the treatment of

membranes, there is essentially no size limitation on the compounds which can be substantially larger than the C₁-C₆ sulfonic acids of the instant invention. The Applicants submit that the commonality of a single functional group within acids does not constitute structural similarity sufficient to teach the small group of compounds claimed in the instant application.

A compound and all of its properties are inseparable. Thus evidence of unobviousness or unexpected advantageous properties may rebut a prima facie case of obviousness based on structural similarities. *In re Chupp*, 816 F.2d 643, 2 USPQ2d 1437 (Fed. Cir. 1987). Therefore, the functional differences in the resultant membranes demonstrate a difference in chemical structure.

II.A.4.d Is there any other teaching to support the selection of the species or subgenus?

No. The subgenus claimed is not taught by the prior art. The Applicants submit that if it were obvious to make the membranes of the instant invention in view of Chau, the membrane would have been made long ago as the Chau patent was issued in 1991. Therefore, the claim must be nonobvious under 103(a).

Rejections under 35 U.S.C. 103(a) over Chau in view of Koo

The Examiner has rejected claims 21, 23 and 25 as being unpatentable over Chau in view of Koo under 35 U.S.C. 103(a). The Examiner states that a case of *prima facie* obviousness may be made when the chemical compounds have very close structural similarities and similar utilities. The Examiner states that it would be obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Koo in conjunction with the teachings of Chau to make polyamide reverse osmosis membranes, because Koo teaches that these sulfonic acids are equivalent for providing high flux, high rejection membranes.

The Examiner has pointed to three of the many sulfonic acids listed in Koo,

specifically methane sulfonic acid, ethane sulfonic acid and benzene sulfonic acid, and has stated that it would be obvious to use these acids in the context of Chau. Again, the Applicants submit that there are no teachings in Koo to suggest the use of these sulfonic acids of the many sulfonic acids listed. These arguments are presented in the paragraph bridging pages 8 and 9 in the communication of January 22, 2004. The Applicants further present an analysis based on the flow chart in the MPEP to demonstrate the lack of sufficient information in Koo to select the specific compounds claimed in claims 21, 23, 25, 28, 34, 35 and 37. Again, text from the MPEP is in italics.

II.A.4.a. Is Genus So Small That Each Member is Inherently Disclosed?

No. Koo teaches a number of large classes of compounds. The Applicants submit that a preparation of an exhaustive list of all of the compounds that would fall within the classes listed by Koo would be a substantial undertaking. (see *In re Jones*) Therefore the small group and the specific sulfonic acids claimed are not obvious in view of the prior art.

II.A. 4.b Are There Express Teachings That Would Have Motivated the Selection?

No. Many classes of compounds are taught. In order for the instant invention to be obvious in view of Koo, one would have to be motivated to select the specific compounds recited in the claims listed above. This would mean selecting some of the poorest performing membranes listed in Table 1 of Koo. The Applicants have calculated the flux of the membranes in Koo under the salt and pressure conditions given in the claims. The membranes treated with compounds that fall within the limitations of the claims, MSA and TSA, result in membranes with fluxes from 7.2 gfd to 10.1 gfd. These numbers are substantially lower than those required by the claims. (see *Douglas Aircraft Co., Inc. v. Mueller*) Therefore, the operativeness of the compounds claimed in the method of the invention are surprising in view of the teachings of the prior art. Therefore, the selection is not obvious.

The only membrane that meets the flux requirements of the instant invention is made using TSA, which is not included in either the independent claims, or in the claims

that are rejected under Koo. By reviewing the Koo reference *as a whole*, as is required by the MPEP (see section 2141.02), one would be motivated to use the higher molecular weight compounds, specifically the aryl compound TSA that provides the four membranes with the highest fluxes, 11.7gfd to 16.3 gfd. One would not be motivated to select the compounds that result in membranes with fluxes that are only about 50-70% of what is required by the claims.

II.A.4.c. Is there a teaching of structural similarity?

No. The list of strong acids provided by Koo in themselves do not have substantial structural similarity. Therefore, one could not select the specific compounds taught in claims 21, 23, 25, 28, 34, 35 and 37 based on structural similarity to the compounds used in Koo. (see *In re Chupp*) The functional difference of the compounds strongly suggests a structural difference in the final membranes.

II.A.4.d Is there any other teaching to support the selection of the species or subgenus?

No. In fact Koo teaches away from the use of the lower molecular weight sulfonic acids due to their poor performance in his assays. There is no motivation to select the compounds claimed

In re Mercier, 185 USPQ 774, 778 (CCPA 1975) the Court held that:

The relevant portions of a reference include not only those teachings which would suggest particular aspects of an invention to one having ordinary skill in the art, but also those teachings which would lead such a person away from the claimed invention. See *In re Lunsford*, 53 CCPA 986, 357F.2d 380, 148 USPQ 716 (1966)... Without the benefit of the appellant's disclosure, a person having ordinary skill in the art would not know what portions of the disclosure of the reference to consider and what portions to disregard as irrelevant or misleading. See *In re Wesslau*, 53 CCPA 746, 353 F.2d 239, 147 USPQ 391(1965).

The Applicants submit that there is no motivation to elect the compounds claimed in the instant invention in light of the teachings of Koo.

The Applicants further submit that the use of the strong acids, including sulfonic acids, in Koo is not the same as the use of sulfonic acids in Chau; therefore, there is no motivation to combine the references. Again, the holdings of the Court in *In re Rouffet*, Fed. Cir., No. 97-1492 (1998) are relevant. There is no motivation to combine the references. The breadth of the lists of compounds taught by both applications are far too general to teach the specific methods of the instant invention. (See *In re Jones*)

The sulfonic acids in Koo are used as a reactant to make a salt with a polyfunctional amine to make the membrane, not as a post-treatment for a completed membrane. The Summary of the Invention of Koo states (col 2, ln 64ff):

According to one aspect of the present invention, there is disclosed a polyamide membrane, said polyamide membrane comprising a reaction product of (i) a polyfunctional amine and (ii) an amine-reactive reactant selected from the group consisting of a polyfunctional acyl halide, a polyfunctional sulfonyl halide and a polyfunctional isocyanate (iii) in the presence of a salt-containing compound, said salt containing compound being a reaction product of a strong acid and a polyfunctional amine. [emphasis added]

In Koo, the strong acid is used to make a salt, not to treat a membrane.

Sulfonic acid is used in Chau to treat membranes. The Summary of the Invention of Chau (col 3, ln 36-50) reads:

In one aspect an embodiment of this invention resides in a high flux semipermeable membrane prepared by coating a porous support backing material with an aqueous solution of a polyamine, removing excess solution, contacting the coated porous support backing material with an organic solvent solution of a polyacyl halide, polysulfonyl halide or polyisocyanate to form a reaction product within and/or on the surface of said porous support backing material, treating the resultant composite with a solution of an acid [emphasis added] or amine salt selected from the group consisting of hydroxypolycarboxylic acids, polyaminoalkylene polycarboxylic acids, sulfonic acids, amino acids, amino acid salts, amino salts of acids, polymeric acids and inorganic acids, drying and recovering the resultant high flux semipermeable membrane.

Koo uses a "salt containing compound" that is the reaction product of a strong acid and a polyfunctional amine to make membranes. The salt containing compound used in the preparation of the membrane does not contain a strong acid. Koo does not use strong acids directly in the preparation of membranes. Koo does not use strong acids in the treatment of membranes.

Chau teaches the treatment of membranes with any of a number of compounds including sulfonic acids to treat membranes to allow to "enable the membrane to be stored in a dry manner prior thereof to use in separation process." (abstract) The Applicants submit that one of ordinary skill in the art would not consider the preparation of a salt and the treatment of membranes to be similar utilities. In Koo, the acid is never used directly with the membrane. If the salt and the acid were functionally similar, Koo would not be motivated to make the salt. Clearly this is not the case. Therefore, the use of the sulfonic acid in Chau and Koo cannot be considered similar. Therefore, the combination of references is improper and the rejection is traversed. The Applicants submit that claims 21, 23 and 25 should now be allowable, and the rejection under 35 USC 103(a) is traversed. Similarly the newly added claims are also not obvious in view of the prior art.

Secondary Considerations

A rejection under 35 U.S.C. 103 must take into consideration the fundamental inquiries set forth in *Graham v. John Deere* including the scope and content of the prior art, the difference between the prior art and the claims at issue and the level of ordinary skill in the pertinent art at the time the invention is made. In fields such as chemistry where accomplishments tend to be incremental, it can be difficult to avoid hindsight and determine what might have been obvious to one of ordinary skill in the art at the time of filing. Invention does not require a flash of genius, but instead simply a useful advance.

Objective evidence of secondary considerations may in any given case be entitled to more or less weight, depending upon its nature and its relationship to the merits of the invention. It may be the most pertinent, probative, and revealing evidence available to the decision maker to recognize that the evidence of secondary considerations may be particularly strong and entitled to such weight that it may be decisive. (*Ashland Oil, Inc. v. Delta Resins & Refracs., Inc.*, 776 F. 2d 281, 227 USPQ 657 (Fed. Cir. 1985). The Applicants submit that the secondary considerations deserve substantial weight in this case as the products at issue in the case are the membrane of the claims of the instant invention and the membranes made by the owner of the main reference in the case (see Declaration of the Inventor).

To provide better perspective on what would have been obvious, secondary considerations may be used to determine the non-obviousness of the invention. These considerations include, but are not limited to:

- (a) commercial success;
- (b) long felt, but unresolved need;
- (c) failure of others;
- (d) recognition of problem;
- (e) failed attempts to solve problem;
- (f) simultaneous, independent invention by others;
- (g) competitors prompt copying;
- (h) acclaim by others;
- (i) licensing of patent to industry;
- (j) teaching away by those skilled in the art; and
- (k) results of invention unexpected by skilled.

Secondary considerations were found to be critically important in a recent Federal Circuit case of *Ecolchem, Inc v. Southern California Edison Company*.

Ecolochem sued Southern California Edison for infringement of its patent (USP 4,818,411, hereafter the '411 patent). Southern California Edison responded by saying that the patent was invalid as it was obvious in view of the prior art. The court relied heavily on secondary considerations to provide a view of what was obvious to one skilled in the art at the time of the invention and found that the Ecolochem patent was non-obvious in view of the prior art despite the fact that it was a combination of methods that were all well known at the time of the filing of the application. Southern California Edison was found guilty of willful infringement.

The Ecolochem '411 patent taught the combination of a number of methods that were all well known at the time of the filing of the application. The use of hydrazine to remove dissolved oxygen from water was well known. The reaction was known to be slow at room temperature. Activated carbon was known to be useful as a catalyst. However, the use of activated carbon results in water with an unacceptably high level of contaminants for use in nuclear power plants. It was discovered by the inventors that the use of ion exchange resins, well known at the time of the application, allowed for the removal of carbon contaminants and the unreacted hydrazine, resulting in water that could be used for the desired application. Although the individual steps were not novel, their combination was found to be novel and non-obvious in view of the prior art. Therefore, a patent was issued. The invention was well received by those in the industry and resulted in substantial commercial success for Ecolochem. Ecolochem made sales to over 25 power plants and earned over \$10 million in revenue in its first seven years. These factors were considered by the court to be significant in the determination that the patent had been properly granted and that the claims were, in fact, novel and non-obvious in view of the prior art.

The Applicants submit that the Ecolochem v. Southern California Edison case is relevant to this case. Treatment of filtration membranes is known to those

skilled in the art. Sulfonic acids, including those specifically claimed in this application, are well known to those skilled in the art. However, the treatment of filtration membranes with the sulfonic acids specified by the claims of the invention to result in a membrane that is superior to other commercially available membranes, resulting in commercial success of the membrane and acclaim from those in the industry.

The Applicants have enclosed three documents to support the non-obviousness of the instant invention based on secondary considerations. These documents demonstrate commercial success of Hydranautics based on the membranes of the invention. This success was due to an unmet need in the industry and the failure of others to provide membranes with the appropriate functional characteristics. The commercial success of Hydranautics has been coupled with acclaim from those in the industry who have independently tested the membranes of the invention against other commercially available membranes and have found them to be superior.

The membranes of the instant application have achieved substantial commercial success despite their higher direct cost when compared to other commercially available membranes designed for a similar use. The Applicants have enclosed three published manuscripts, each demonstrating the advantages of their membranes as determined by others in the industry. A declaration from the Inventor is enclosed stating that the ESNA-LF membranes discussed in the references are those of Hydranautics. This declaration provides a nexus between the references and the claims at issue in the instant application. The declaration further states that the first knowledge of the membrane by others is January 19, 2000 and the earliest possible first use by others is January 28, 2000. This is less than one year before the filing date of the application on November 28, 2000.

In view of the rejections of the claims for anticipation and obviousness in view

of Chau, it is notable that one of the other membranes tested was provided by Koch, the owner of the Chau patent. Despite having the knowledge of the teachings of Chau and 10 years time, it was not obvious to Koch and their employees, some of whom are likely skilled in the art of membrane preparation, how to make a membrane using the teachings of the Chau patent to satisfy the requirement of the water treatment plants. The desire for commercial success of the company would provide sufficient motivation to try to make the highest performance membranes possible. The following references demonstrate the failure of Koch, strongly suggesting a lack of teachings in the Chau reference. However, the Applicants submit that the secondary considerations need not be directed to the differences between the references cited by the Examiner and the instant claims. Instead, secondary considerations hold the invention of the claims up to the other products made with the skill in the art at the time of, or frequently after the filing of the application. The skill in the art at the time of the testing clearly included the almost ten year old patent of Chau along with many other patent and non-patent references related to membrane technology.

The Applicants first wish to direct the Examiner's attention to the paper entitled "Optimizing the Performance of Low Fouling Membranes for the World's Largest Nanofiltration Plant" by Kiefer et al, presented at the American Water Works Association 2003 Annual Conference, March 2-5 (Appendix D). It should be noted that the authors of the paper are not affiliated with Hydranautics and that the data in the paper were obtained independent of Hydranautics. The membrane of the instant invention is designated at the ESNA LF membrane. The manuscript details the analysis performed by the City of Boca Raton, Florida to determine what membranes would be used in their new water purification plant. After an extensive analysis, and much to the surprise of those performing the analysis, the Hydranautics membranes were selected.

The details of the testing are provided in the figures. Figure 1 is a graph of Mass Transfer Coefficient vs. Time of Operation for three commercially available membranes, not including the membrane of the instant invention. None of the membranes were found to be acceptable despite the use of a variety of combinations of acids and antiscalants (paragraph immediately preceding Figure 1). Figure 2 shows a surprising improvement seen with the commercially available membranes without pretreatment with acids or antiscalants; however, the mass transfer coefficient was not as high as would have been preferred. Therefore, other sources of membranes were sought out for testing.

A prototype membrane from Hydranautics was tested (page 4, new low fouling membrane). The data are presented in Figure 3 and show better performance than the membranes tested in Figure 2. In the text it is noted that the prototype Hydranautics membranes were stable for six to eight months without the addition of acid or antiscalant.

Side by side testing of the Hydranautics membrane for calcium passage against three other commercially available membranes is shown in Figure 4. Figure 5 is again a graph of mass transfer coefficient over time comparing the Hydranautics membrane to the best performing membrane in the previous test. Again, the Hydranautics membrane outperformed the other commercially available membrane.

A summary of the advantages of the Hydranautics membrane are presented in the bullet points in the middle of page 10. However, the strongest demonstration of the uniqueness of the membranes of the instant invention is shown in the first full paragraph on page 10. The membranes of Hydranautics were not initially included in the testing due to capital cost considerations. However, none of the commercially available membranes were able to function at a sufficient level to meet the requirements of the plant. Therefore, the Hydranautics membranes were finally

selected for their outstanding performance, and overall cost savings due to this high level of performance. The City of Boca Raton placed an order for 7690 elements for a total cost of \$4.2 million for the first year of operation. This is a substantially larger number of elements than would typical water purification plant which uses about 200 to 950 elements per year.

The paper "Optimizing New Low Fouling Nanofiltration Membrane Performance for Deerfield Beach" by Kiefer et al. (presented at the American Water Works Association 2003 Annual Conference, March 2-5) (Appendix E) presents another location wherein the ESNA LF membranes of Hydranautics were demonstrated to function at a substantially superior level to other commercially available membranes in a hybrid system. Again, the manuscript was not written by an employee of Hydranautics, demonstrating the enthusiasm with which the membranes were accepted by those in the industry. In a first direct comparison, the ESNA LF membrane was shown to be far more stable than the two membranes tested for a hybrid water purification system (see Figure 3), demonstrating the failure of others to produce a membrane with the necessary characteristics. The water product generated by the Hydranautics single membrane process fell slightly outside the parameters required by the Deerfield Beach plant, so a hybrid membrane system was developed using the membranes of the instant invention. Again, due to the high quality of the membranes of the instant invention, the higher cost of the membranes was negated by the substantially improved performance. The Deerfield Beach system is further discussed in the manuscript entitled "Advantages of New Low Fouling Nanofiltration Membranes vs. a Hybrid Membrane Design for Deerfield Beach" by Kiefer and Jackson presented at the American Water Works Association 2002 Annual Conference, June 16-20 (Appendix F). The City of Deerfield Beach placed an order for 2016 elements for a total cost of \$900,000.

The Applicants submit that the attached references demonstrate the non-obviousness of any method to make membranes that meet the requirements of the claims of the instant application. It is not known by the Applicants what methods were used for the preparation of the membranes tested in the attached references.

Commercial success has clearly been demonstrated. An unmet need in the industry has been clearly demonstrated. The failure of others, notably the owners of the Chau patent, to meet the need has been clearly demonstrated. Acclaim by those in the industry has been clearly demonstrated.

A prototype membrane from Hydranautics was tested as none of the commercial membranes tested were able to meet the needs of the plants. The publication of the papers by others, not by Hydranautics, demonstrates that they were well received by the industry and acclaimed for their benefits. As stated above, if the results of the treatment of the membranes was obvious, it would have been done long ago as the Chau patent was issued in 1991. Therefore, many of the secondary considerations have been satisfied regarding the novelty and non-obviousness of the instant invention. Therefore the rejection of the claims is overcome and the new claims are neither anticipated nor obvious in view of the prior art.

DISCLOSURE PRIOR TO THE CRITICAL DATE

The Examiner noted that Figure 3 of the Keifer 2002 reference was dated 8/31/00. As the graph indicated testing of the membrane for 32 days meaning that the membrane had been available for at least a month prior to the date on the graph. The Examiner requested that the Applicants state the first date of disclosure or offer for sale of the membrane of the invention.

The membrane of the invention was first requested for testing by the City of Boca Raton on January 19, 2000. The membrane element was shipped on January

28, 2000. This information is included in the attached Declaration of the Inventor. No other documents are available to the Inventor regarding exchanges between Hydranautics and the City of Boca Raton. Therefore, the first use by others is at least two months after the critical date and the first public knowledge of the membrane was at least a month and a half prior to the critical date. Because the critical date is determined retrospectively, those activities that will act as a bar must be of such character that it is apparent at the time that they are conducted that patent filing must be completed within a year. Substantial property rights are at issue, and the trial court must determine with precision when the bar came into being, for the bar must be proven by clear and convincing evidence. (*Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1588, 4 USPQ2d 1210 (Fed. Cir. 1987).

The Inventor stated that it was typical to provide new membranes to potential clients for testing without providing details regarding the specific details of the membranes, such as those listed in the claims. Although the flux and salt passage characteristics of the membranes were known under specific, controlled conditions, the utility of the invention for the plant in Boca Raton could not be determined before testing the membrane with the specific water source for a sustained period. Therefore, the membrane was offered largely for testing purposes.

An inventor may well need to have a customer test the invention to determine whether it works as intended. The 102(b) bar is avoided if the primary purpose of the work was experimental rather than mainly for the purpose of trade or profit. The law recognizes the inventor's need to test the invention, to ascertain whether the work is complete or further changes should be made, and to show that the invention will work for its intended purposes. The law further recognizes that such testing and development may even require disclosure to the public, without barring the inventor's access to the patent system. (*US Environmental Prods., Inc. v. Westall*, 911 F.2d 713, 15 USPQ2d 1898 (Fed. Cir. 1990); *In re Mann*, 861 F.2d 1581, 8 USPQ2d 2030 (Fed. Cir. 1988))

The testing of the membrane of the invention needed to be performed at a water purification plant as that is the ultimate site for use for the membranes. Thus, the testing was required to determine the value of the membranes in a real world setting, rather than in the controlled setting of a lab. Therefore, the January 2000 dates may or may not be considered dates of first disclosure.

FEES

It is believed that no fee is due with this response. New claims have been added, but the total number of claims pending is twenty (20), with two (2) independent claims. However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account 50-1990 referencing case number 7703-PA02.

CONCLUSIONS

In view of the forgoing amendments and arguments, and the attached appendices and references, the Applicants submit that the case is now in proper form for allowance. The Applicants respectfully request that the Examiner withdraw his rejections to claims 15-21, 23 and 25, and allow the newly added claims 27-39.


///

///

If there are any outstanding issues remaining in the case, the Examiner is encouraged to call the Agent for Applicant listed below, collect, to resolve the issues.

Respectfully submitted,

Dated: May 7, 2004

By: 
Colleen J. McKiernan, PhD
Agent for Applicant
Registration No. 48,570

GORDON & REES LLP
1660 Union Street
San Diego, California 92101-2926

Telephone: (619) 238-0999
Facsimile: (619) 238-0062
Docket No.: BHYNA 1028433 (7703-PA02)